AAOS Shoulder & Elbow Registry Launch
FAQs

General Questions

1) What is the relationship between the AAOS Registry Program and each of its anatomical registries?

The Shoulder & Elbow Registry (SER) is part of a family of registries that share the same technical infrastructure, harmonized data element lists, and an ability for participants to track patients longitudinally. Each Registry has its own Steering Committee that provides registry development and management leadership. It is composed of clinical experts and stakeholders in the registry's surgical area.

Much of the structure of the Shoulder & Elbow Registry was replicated from the American Joint Replacement Registry (AJRR), the largest orthopaedic Registry in the world by annual procedural counts. All AAOS registries are built on the RegistryInsights™ platform.

2) How is SER guided and overseen?

SER's Steering Committee members include:

- Gerald R. Williams Jr., MD – Chair
- Joaquin Sanchez-Sotelo, MD
- Ronald A. Navarro, MD
- John E. Kuhn, MD
- Stephen F. Brockmeier, MD – American Orthopaedic Society for Sports Medicine (AOSSM) Representative
- Patrick St. Pierre, MD – American Association of Nurse Anesthetists (AANA) Representative
- Grant E. Garrigues, MD – American Shoulder and Elbow Surgeons (ASES) Representative
- Stephen C. Weber, MD
- Richard F. Seiden, Esq. – Registry Public Advisory Board

3) What is the goal of SER?

SER's goal is to collect shoulder and elbow procedural data provided on patients across the U.S. This data will help improve patient care by providing feedback to participating sites and surgeons, informing the development of performance metrics and standards of care, and supporting quality improvement initiatives, and advocacy across orthopaedics.

Launching in October 2018 with a shoulder arthroplasty module and in 2019, SER will launch modules around rotator cuff repair (spring) and elbow arthroplasty (summer).

4) **What is the value of participating in SER?**
In addition to reducing the overall public cost, joint registries demonstrate up to a 50 percent reduction in revision rates after registry initiation and identification of best practices. There are more than 750,000 total shoulder arthroplasty, rotator cuff repair, and total elbow arthroplasty surgeries performed in the United States each year. An evidence-based registry, like the Shoulder & Elbow Registry, is a cost-effective way to benchmark risk-adjusted data, and provide greater context to patient outcomes comparisons. Identifying improvement needs can potentially mitigate surgical revisions which could lead to millions of dollars in stakeholder savings annually.

5) **What is the price for a subscription to SER if I am a new subscriber to the AAOS Registry Program or if I am already an American Joint Replacement Registry (AJRR) subscriber?**
SER's subscription structure supports a continuously evolving Registry that delivers on our mission to improve orthopaedic care through the collection, analysis, and reporting of actionable data. SER offers a 1-year $3,500 subscription per user. There is an additional one-time $750 configuration fee. Pricing for SER is the same whether you are new to the AAOS Registry Program or already an AJRR subscriber. However, contracting is streamlined if you already subscribe to AJRR. The subscription fee includes access to our robust patient-reported outcome (PRO) platform that you can use to implement and analyze your patient surveys. For questions on pricing and available promotions please contact RegistryInfo@aaos.org.

6) **My institution is interested in joining the AAOS Registry Program, specifically SER, but the subscription fee is not in our budget. Can we still participate?**
Yes, SER participants will only need to pay a modest $750 annual fee to submit data to the Registry. If you would like access to the RegistryInsights™ dashboards, you will need to pay a subscription fee; however, it's considered minimal compared to some other quality initiatives available on the market. If you have a concern about the costs, please contact RegistryInfo@aaos.org.

7) **Is there an additional fee for sending the Registry Procedural File Layout, Post-Operative/Complications File Layout, and/or and Patient-Reported Outcome Measures (PROMs) File Layout data?**
No, all three layouts are included with participation. Additionally, procedural, post-operative, and PROMs layouts for future modules will be included for participants.

8) **How much time does it take to administer the SER program? Will I need to hire any additional employees?**
Assigned full-time employees (FTEs) are not required for participation, but workload will vary depending on the site. AAOS Registry staff will work closely with you to help decrease

the data burden by building queries, or having your technology vendors do so as part of our Authorized Vendor Program. Data specifications and a data dictionary are made for each registry module to provide detailed guidance on how to successfully submit.

9) **How can I access my data in the Registry?**
Accessing your data in the Registry requires that your institution purchase a subscription to our RegistryInsights™ platform. With this subscription, an Authorized User at your institution will receive a username and password that grants them access to your data stored in the Registry.

Users logging in to RegistryInsights™ will be directed to a Registry selection page, where available registries are listed within the Registry Program. Registries that your site are involved with will be listed under "My Registries." Subscribers may access dashboards and reports for registries they are participating in.

Additionally, your data submitters will have permission rights to view and, if needed, correct submission errors. Authorized Users will have access to all the data submitted by your site, reports, and national benchmarks. If you choose to take advantage of our PRO Portal, you can assign someone to be a PROMS Site Administrator, who will have the ability to manage the process of electronically administering and distributing PROs.

10) **Can more than one individual at my site have access to the RegistryInsights™ platform?**
Yes, for a small additional fee, we can provide access rights to additional users beyond your site's primary Authorized User. Contact RegistryInfo@aaos.org to begin the discussion and process of adding an additional Authorized User.

11) **How long does it take to onboard my institution and start participating in the Registry?**
A SER Registry Support Specialist is assigned to work on your site's Registry implementation. Sites can include integrated delivery systems, hospitals, ambulatory surgery centers, and physician private practices. The first essential goal for any site is successful data submission and we will provide you with the knowledge and tools to get you there. It varies by site; however, we partner with you with a goal of being functional within 60 days.

12) **Who will be able to see my site's data?**
Only Authorized Users identified by your site will see your site's data. Only de-identified and aggregate data can be seen externally by other Registry subscribers.

13) **How can I promote my participation in the AAOS Registry Program to my organization's stakeholders?**
Marketing and communications support is available to help promote your site's involvement with the Registry. This includes internal communications with your surgeons and externally with your patients. We will provide a toolkit that includes a logo to indicate participation, as well as a sample press release announcing participation. Through the User Group Network (Unet) you can connect with other Registry participants to learn what has

worked well for their sites. We also provide a slide deck of tables and figures that are published in our Annual Report that you can share with your surgeons.

14) **I may be interested in joining SER. Who do I contact?**
The AAOS Registry Program welcomes your interest in SER. Please contact RegistryInfo@aaos.org or call (847) 292-0530.

Data & IT

1) **How should my data be uploaded to the Registry?**
Data can be sent via an SFTP or HTTPS site or direct upload via the RegistryInsights™ platform. Our secure transfer process implements both an SFTP and a HTTPS service for a site to submit data directly to us. Both services present SER extended validation certificates and automatically encrypt all data upon landing.

If you do not have an SFTP client on your desktop, we suggest using the HTTPS. You may use any web browser to do so. Please note that if you already participate in AJRR, the data submission process is similar.

2) **How can I learn more about Data Specifications?**
SER, will collect three types of data:
- **Procedural File Layout** includes data related to the patient, site, surgeon, and procedure. The layout also consists of elements like comorbidities and length of stay.
- **Post-Operative Complication File Layout** includes 90-day readmission information and enables risk-adjusted outcome comparisons.
- **Patient-reported Outcome Measures (PROMs) File Layout** includes data from surveys submitted by the patient.

The Registry Program converts and compiles data into its own aggregate format, and produces numerous options of comparative reports individualized by facility site, surgeon, procedure, implant, manufacturer, or other value-added criteria.

3) **How often should data be submitted?**
The more frequently data are submitted, the more useful the feedback reports will be. Participants are considered active if they submit every 90 days but we recommend a monthly submission; however, we will accommodate each participant's submission as needed.

4) **Why should I consider a PRO Program?**
A patient-reported outcome (PRO) is defined as any information on the outcome of health care obtained directly from patients without modification by clinicians or other health care professionals. It helps provide a 360-degree view of a patient's healing. One of the ways RegistryInsights™ supports SER is by presenting patient-reported outcome measures (PROMs) collected through a survey process. The survey captures the patient's self-

assessment of their health across a variety of parameters. It is an important tool used in PRO programs. Read "Starting a Goal-Driven Patient-Reported Outcomes Program" for more information.

5) **What follow-up timeframe for PROMs do you recommend?**
PROMs guidelines from groups such as the International Consortium for Health Outcome Measurement (ICHOM) have recommended pre-operative (baseline) and one-year follow-up as appropriate time points for data collection to provide meaningful data for comparing outcomes across providers.

Each time point will have a two-month window for data collection. SER's platform will allow for other time points (e.g., three-month, six-month, etc.) to be submitted and stored in SER's database should you wish. However, national benchmarks will only be reported for pre-operative and one-year outcome.

6) **Can you accept all file layouts for retrospective data?**
Yes. We accept retrospective data for SER from all three file layouts which includes the Procedural File Layout, the Post-Op Complication File Layout, and the Patient-Reported Outcome Measures (PROMs) File Layout. Sending more data adds to your institution's data set and creates a more robust Registry. You can send retrospective data in all three layouts from 1/1/2016 moving forward.

7) **How do you make sure patient information is linked for longitudinal patient follow-up and outcomes?**
We collect unique patient identifiers, like Social Security numbers, to ensure individual patients are properly identified. This allows us to track and link multiple procedures to the same patient. Revisions and additional procedures may not be done by the same surgeon or at the same hospital, so a unique patient identifier is critical. It will also assist in tracking potentially poor performing implants as well.

8) **What type of training do you provide for the RegistryInsights™ platform?**
SER participants receive a User Guide that provides a step-by-step process for accessing and utilizing the RegistryInsights™ system. General platform training and PRO platform training webinars are also held periodically to inform Registry users on how to use the platform. And, if one-on-one training or additional demonstrations are needed, we are happy to assist you.

9) **How do you keep the data in the Registry secure?**
We take data privacy and security very seriously and follow all HIPAA privacy rules and Protected Health Information (PHI) regulations. Our PHI is secured, maintained, and released in accordance with all applicable federal and state laws, rules and regulations, including the HIPAA Regulations. All our personnel who process, generate reports, or otherwise have contact with PHI must uphold the patient's right to confidentiality. This policy refers to all information resources, whether written, verbal, or electronic, and whether individually

controlled, shared, stand alone, or networked. Additionally, our staff have been trained in HIPAA privacy and security through the Collaborative Institutional Training Initiative (CITI).

10) **Do you provide ongoing training to Registry Users once they complete their onboarding process?**
We are committed to providing training to ensure all our sites are comfortable with the data submission process. We do this through our Registry Support Specialists who will provide you with the necessary tools to do so. We will work at your speed until you are well trained, and if one-on-one training or additional demonstrations of the RegistryInsights™ platform are needed, we are happy to assist you.

Legal

1) **Which agreements are required to join SER?**
Two agreements need to be signed – Business Associate Agreement/Data Use Agreement (BAA/DUA) and Participation Agreement. The Participation Agreement is required and outlines most of the terms and conditions of the SER/site relationship, for example: how and when data should be submitted, term and termination, fees, ownership and confidentiality of data, and other terms and conditions for participation. The BAA/DUA Agreement is required to comply with our joint responsibilities as covered entity (the site) and SER, as your business associate and recipient of a limited data set, as required by the Health Insurance Portability and Accountability Act of 1996.

2) **Will each site's Institutional Review Board (IRB) need to review this project and/or obtain informed consent from patients?**
Each site should check with their local IRB representative, but SER has obtained a program IRB approval for waiver of consent. Please contact us at RegistryInfo@aaos.org if you have further questions or need assistance with documentation for your site.

To learn more, please contact a Registry Engagement Associate
(847) 292-0530 | RegistryInfo@aaos.org

Or learn more at www.aaos.org/registries/ser